SGLT2 Step Policy

**Description**

Farxiga (dapagliflozin), Glyxambi (empagliflozin/linagliptin), Jardiance (empagliflozin), Qtern (dapagliflozin/saxagliptin), Qternmet XR (dapagliflozin/saxagliptin/metformin), Synjardy, Synjardy XR (empagliflozin/metformin), Xigduo XR (dapagliflozin/metformin)

**Background**

Farxiga (dapagliflozin), Glyxambi (empagliflozin/linagliptin), Jardiance (empagliflozin), Qtern (dapagliflozin/saxagliptin), Qternmet XR (dapagliflozin/saxagliptin/metformin), Synjardy, Synjardy XR (empagliflozin/metformin), and Xigduo XR (dapagliflozin/metformin) are oral sodium-glucose co-transporter 2 (SGLT2) inhibitors indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. They should not be used to treat type 1 diabetes; in those who have increased ketones in their blood or urine (diabetic ketoacidosis); or in those with severe renal impairment, end stage renal disease, or in patients on dialysis. They work by blocking the reabsorption of glucose by the kidney, increasing glucose excretion, and lowering blood glucose levels in diabetics who have elevated blood glucose levels.

**Regulatory Status**

FDA-approved indications for Farxiga, Glyxambi, Jardiance, Qtern, Qternmet XR, Synjardy, Synjardy XR, and Xigduo XR: They are sodium-glucose co-transporter 2 (SGLT2) inhibitors indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Farxiga, Glyxambi, Jardiance, Qtern, Qternmet XR, Synjardy, Synjardy XR, and Xigduo XR may be considered medically necessary for patients who have had an inadequate response, intolerance or contraindication to metformin.

Step Edit Requirements

Patients who have filled metformin in the past 1 year are exempt from these PA requirements.

Diagnosis

Patient must have the following:

Patient has had an inadequate response, intolerance, or contraindication to metformin

Policy Guidelines

Prior - Approval Limits

Duration 12 months

Rationale

Summary

Farxiga (dapagliflozin), Glyxambi (empagliflozin/linagliptin), Jardiance (empagliflozin), Qtern (dapagliflozin/saxagliptin), Qternmet XR (dapagliflozin/saxagliptin/metformin), Synjardy, Synjardy XR (empagliflozin/metformin), and Xigduo XR (dapagliflozin/metformin) are oral sodium-glucose co-transporter 2 (SGLT2) inhibitors indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. They should not be used to
treat type 1 diabetes; in those who have increased ketones in their blood or urine (diabetic ketoacidosis); or in those with severe renal impairment, end stage renal disease, or in patients on dialysis. They work by blocking the reabsorption of glucose by the kidney, increasing glucose excretion, and lowering blood glucose levels in diabetics who have elevated blood glucose levels.

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Farxiga, Glyxambi, Jardiance, Qtern, Qternmet XR, Synjardy, Synjardy XR, and Xigduo XR while maintaining optimal therapeutic outcomes.

### Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>November 2018</td>
<td>Addition to PA</td>
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<tr>
<td>May 2019</td>
<td>Addition of Qternmet XR and revised lookback statement to only include metformin</td>
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<tr>
<td>June 2019</td>
<td>Annual review</td>
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### Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.